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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,278	10/08/2003	Syed Faiyaz Ahmed Hossainy	50623.342	9337

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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04/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/682,278	Applicant(s) HOSSAINY, SYED FAIYAZ AHMED	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,24,28-32,35,36,39,41-45,48,50,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,24,28-32,35,36,39,41-45,48,50,52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 23, 29, 30, 32, 35, 36, 39, 41, 45, and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (US 5,788,979) in view of Georger, Jr. et al. (US 5,510,628; "Georger"). Alt discloses a stent comprising a substrate and a coating thereon, the coating including a first layer connected to the stent substrate, the first layer made of a first polymer and a second layer made of a second polymer. Alt discloses that the multiple layers may be placed in juxtaposition within a single layer (col. 9 ll. 50+, exp. col. 9 ll. 65- col. 10, ll. 3) and, instead of multiple layers, the coating layer can differ in constituency of additive depending on its particular orientation on the stent (col. 6 ll. 13-16). Alt does not expressly disclose alternating back and forth between the layers and thus discontinuous layers. However, Georger discloses that micro-patterning the surfaces of medical implants to have an alternating coating is well known in the

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art (see fig. 1c, 5a). Since such an alternating configuration is known in the art in view of Georger, it would have been obvious to one skilled in the art to substitute layers in juxtaposition that do not necessarily alternate back and forth as taught by Alt with an alternating coating as taught by Georger since such a modification appears to be a simple substitution of one known configuration for another wherein a single coating layer is formed of multiple sections having different compositions, which fails to patentably distinguish the prior art from the art of modified Alt.

4. Regarding claim 45, each layer includes a different active ingredient (col. 9, ll. 50-col. 10, ll. 4 of Alt).

5. Regarding claims 29 and 39, the release rates of the active ingredients can be controlled by the choice of polymeric carrier (col. 4 ll. 14-29; col. 5 ll. 29-34 of Alt). It would have been obvious to use different release rates for the different layers that are in alternating juxtaposition since Alt teaches that different release rates are advantageous for different treatments.

6. Regarding claims 30 and 36, the stent is radially expandable (col. 11, ll. 28-30 of Alt) and may be metallic or polymeric (col. 6 ll. 37-38 of Alt).

7. Regarding claim 53, it would have been obvious to one skilled in the art to use a solvent in the second layer that does not adversely affect the therapeutic substance of the first layer as such a material choice can be considered common sense.

8. Regarding claims 32 and 35, modified Alt discloses the invention substantially as stated above but fails to disclose that the alternating sections have a width of about 5 microns to about 500 microns. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the width of the alternating sections of about 5 to about 500 microns because Applicant has not disclosed that this particular width range provides an advantage, is used for a particular purpose, or solves a stated problem over

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sections with widths falling out of this range. One of ordinary skill in the art, furthermore, would have expected modified Alt's invention and applicant's invention, to perform equally well with a spacing falling within the range of about 5 to about 500 microns or outside this range since no criticality is disclosed for this particular range. Therefore, it would have been a prima facie obvious to further modify Alt to obtain the invention as specified in claims 32 and 35 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Alt in view of Georger.

9. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Georger as applied to claim 23 above and further in view of Tang et al. (US 5,412,068; "Tang"). Alt in view of Georger discloses the invention substantially as stated above except for the addition of a radiopaque substance in the first or second layer. However, Tang et al. makes obvious the inclusion of a radiopaque substance in the coating (col. 20, ll. 30-34 and 45-48) and it would have been well within the purview of one skilled in the art to include such a substance in order to facilitate imaging of the implanted stent.

10. **Claims 24, 28, 42, 44, 48, 50, and 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Georger as applied to claims 23 and 41 above, and further in view of Fearnot et al (US 5,609,629; "Fearnot"). Alt in view of Georger discloses the invention substantially except for a primer layer disposed between the substrate and the first and second layers and a third layer covering at least a portion of the first and second layers to control the rate of release of the active ingredients.

11. Fearnot teaches that primer layers are well known in the art ("16"; col. 9 ll. 64- col. 10, ll. 16). Such a primer layer isolates the stent from the body after the drug delivery coating has been degraded. It would have been obvious to one skilled in the art to have modified Alt to include a primer as taught by Fearnot in order to protect the stent and the patient's vessel from

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each other once the coating has been degraded from the stent. Fearnot also teaches a third layer that forms a top coat over a coating which includes active ingredients. This top coat is advantageous as it allows further control over the release of the active ingredients from the coating. It would have been obvious to one skilled in the art to have modified Alt to include such a third layer as taught by Fearnot so that it too has this advantage.

12. **Claim 43** is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Georger as applied to claims 23 and 41 above, and further in view of Ding (US 5,837,313). Alt in view of Georger discloses the invention substantially but fails to expressly disclose using different polymers for each layer as well as using the same active ingredient in each layer.

13. Ding teaches that it is well known to tailor release rate profiles by using different matrix polymer materials in different layers and it would have been well within the purview of one skilled in the art to use such a method to control the release rate of the materials of Alt. Ding also teaches that is well known to incorporate the same bioactive material into different layers (fig. 2 which shows two layers containing heparin), with each layer having different amounts of the bioactive material. This is advantageous when a single drug needs to be delivered at different rates over time. It would have been obvious to use such a configuration for the device of Alt so that it too would have this advantage.

Response to Arguments

14. Applicant's arguments filed 1/12/2009 have been fully considered but they are not persuasive. Applicant argues that it would not have been obvious to substitute the alternating configuration of layers taught by Georger for the juxtaposed layers of Alt (that do not necessarily alternate but rather only have a first and second layer next to each other) because the substitution would not have predictable results. The examiner respectfully disagrees. For example, adding an additional area of each of the first and second layers juxtaposed next to the

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two juxtaposed layers disclosed by Alt to give an alternating configuration will not change the function of the coating. Since Georger discloses that this configuration is well known for coatings on an implantable medical device, it would have been obvious to one skilled in the art to try such a configuration since one skilled in the art has good reason to pursue the known technical options within his or her technical grasp. If this leads to the anticipated success, it is likely the product of ordinary skill and common sense. Applicant argues that the substitution would not have predictable results because Georger teaches applying an ultra-thin film while Alt teaches a thicker coating that is applied by spraying or dipping. However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Georger makes obvious an alternating pattern for coating a stent and one skilled in the art would recognize that different methods of coating the stent can be used to achieve this alternating pattern and it would have been within the purview of one skilled in the art to employ different, known methods capable of applying the coating of Alt in the pattern suggested by Georger.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 4/1/2009

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/1/09